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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/389,782 | 09/03/1999 | COLIN R. DUNSTAN | A-604 | 5852 |

21069 7590 04/05/2002

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EXAMINER

HELMS, LARRY RONALD

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

1642

DATE MAILED: 04/05/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/389,782

Applicant(s)

DUNSTAN ET AL.

Examiner

Larry R. Helms

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 November 2001.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 21-31 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 21-31 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

1. Claims 1-20 have been canceled.
Claims 21-31 have been added.
2. The text of those sections of Title 35 U.S.C. code not included in this office action can be found in a prior Office Action.
3. The following Office Action contains some NEW GROUNDS of rejection.

Claim Objections

4. Claim 22 is objected to because of the following informalities:
 - a. Claim 22 needs to have "SEQ ID NO:1" inserted after "Figure 1" in line 3 of the claim. Claim 22 should contain SEQ ID Nos for the sequences encompassed by the sequence rules.

Appropriate correction is required.

Rejections Withdrawn

5. The rejection of claims under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn in view of arguments and amendments to the claims.

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6. The rejection of claim 1 (which is encompassed by newly added claim 21) under 35 U.S.C. 102(e) as being anticipated by Boyle et al (U.S. Patent 6,015,938, filed 11/18/97 which is a divisional which has a filing date of 12/22/95) is withdrawn in view of the amendment to the claim.

Response to Arguments

7. The rejection of newly added claims 21-25, 26-31 under 35 U.S.C. 112, first paragraph, is maintained and made again.

The response filed 11/21/01 has been carefully considered but is deemed not to be persuasive. The response states there are numerous examples of OPG fragments in the art which have biological activity as well as OPG variants and Fc fragments and variants (see page 6 of response). In response to these arguments, the claims are not directed to variants and fragments which retain biological activity. While it may be true that the art teaches variants and fragments that are biologically active, the claims do not require biological activity. The definition of variants and fragments in the specification at page 8, lines 19 to page 9 state "variant" as a polypeptide "comprising an amino acid sequence which contain one or more amino acid sequence substitutions, deletions, and/or additions". This definition encompasses any change even to a protein that would not be a OPG protein and the claims do not require a functioning protein or a protein to function as an Fc or OPG, therefore, while it may be true that one skill in the art could make fusion proteins as broadly claimed, one would require undue experimentation to determine how to use such proteins absence a function.

8. The rejection of newly added claims 21 and 23 under 35 U.S.C. 102(b) as being anticipated by Boyle et al (WO 97/23614, published 7/3/97, IDS #6) is maintained and made again.

The response filed 11/21/01 has been carefully considered but is deemed not to be persuasive. The response states "The new claims recite a fusion protein comprising an OPG variant or fragment fused at its N-terminus to the C-terminus of an Fc protein" (see page 6 of response). In response to this argument, Boyle et al teach a fusion protein comprising an OPG variant 22-401 fused at its N-terminus to the C-terminus of the Fc protein (see page 105, lines 19-25).

9. The rejection of newly added claims 21-31 under 35 U.S.C. 103(a) as being unpatentable over Mann et al (WO 98/28427, published 7/2/98, IDS #6) and further in view of Boyle et al (U.S. Patent 6,015,938, filed as a divisional with a filing date of 12/22/95) is maintained and made again.

The response filed 11/21/01 has been carefully considered but is deemed not to be persuasive. The response states "there is no suggestion in the references that substituting an OPG protein for an OB protein in the disclosed fusion protein would lead to advantageous properties for the OPG protein" (see page 7 of response). In response to this argument, Mann et al clearly teaches the advantages of fusion of the Fc at the N-terminus to the protein which demonstrated advantages of stability, clearance rate and decreased degradation which was not seen in the fusion protein of the Fc to the C-

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terminus of the protein (see page 4, lines 15-35). Thus the advantages as taught by Man et al would lead one skill in the art to obviously produce the fusion protein as claimed in the Fc-OPG orientation. One skill in the art would obviously use the OPG protein because Boyle et al teach Fc fusions with OPG for purification and Mann et al teach the advantages such as stability and decreased degradation.

Conclusions

10. No claims are allowed.

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

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12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Larry R. Helms, Ph.D, whose telephone number is (703) 306-5879. The examiner can normally be reached on Monday through Friday from 7:00 am to 4:30 pm, with alternate Fridays off. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached on (703) 308-3995. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

13. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 308-4242.

Respectfully,

Larry R. Helms Ph.D.

703-306-5879


SHEELA HUFF
PRIMARY EXAMINER